

APPENDIX XII**PROJECT DOCUMENT****PROPOSAL FOR NEW WORK ON THE DEVELOPMENT OF GUIDANCE FOR MONITORING THE STABILITY AND PURITY OF REFERENCE MATERIALS AND RELATED STOCK SOLUTIONS OF PESTICIDES DURING PROLONGED STORAGE****Purpose and Scope of New Work**

1. Pesticide residues in food commodities have become a worldwide agricultural trade-concern, which has led to enforcement of strict pesticide regulations. More than 1200 pesticides are used to control the pests on different food commodities. Analyses of pesticides in the food chain requires the use of specific Reference Materials (RMs) of known chemical purity within the expiry dates specified by the Reference Material Producers (RMPs) to ensure the reliability of the test results. However, limited shelf lives, and hence high recurring cost of RMs act as major impediments for performing regular pesticide residue analysis. These problems are magnified for multi-pesticide residue analysis by testing laboratories situated in developing countries as they are required to allocate a large part of their funds to the frequent procurement of expensive RMs as their use is restricted by the expiry dates specified by the RMPs in the certificates of analysis (CoAs). Many times, countries cannot afford frequent purchase of high-cost RMs for their pesticide residue control work.
2. Furthermore, due to supply chain constraints, some laboratories receive RMs close to their expiry date as per the CoAs. In such situations the laboratories are forced to buy new standards and prepare new stock solutions more frequently than necessary. This leads to insurmountable extra work and increased laboratory costs, especially for compounds for which stability is well-understood. Additionally, shipping of RMs by the suppliers to laboratories increase the acquisition time for procurement, creating hurdles in sustainable pesticide residue control program.
3. Many RMs stay stable even after the expiry dates stated in the CoAs with no change in the purity. Some studies have also reported that if RMs are stored at better storage conditions than recommended by the manufacturer, the RMs are stable for much longer than the expiry dates indicated by the RMPs. Such RMs may technically be allowed to be used beyond their expiry dates if laboratory checks are in place to demonstrate that they are stable and continue meeting the purity requirements. However, the lack of data on the stability and purity of RMs during prolonged storage and absence of guidance procedures for monitoring these prevent their use beyond the expiry dates.
4. The proposed guidance on monitoring the stability and purity of RMs will allow the extended use of the RMs which are stable with acceptable purity beyond their expiry dates specified by RMPs for robust pesticide residue analysis. These guidelines will be applicable to RMs (solids/liquids) and their stock solutions.

Relevance and Timeliness of the Work

5. RMs with specified purity are required not only for accurate qualitative and quantitative analysis of pesticide active ingredient(s) in technical products and formulations, stock solutions, but also for accurate determination of pesticide residues in food commodities for food safety control, fixation of pesticide MRLs, overcoming the related trade barriers and various other purposes.
6. It is known that many RMs retain their purity even after their expiry dates specified by the RMPs, and hence may continue to be used after verification of their purity as specified in the CoAs. However, currently there has been no Codex guidance on extending the use of RMs beyond their expiry dates which can be widely adopted by pesticide residue laboratories worldwide.
7. The proposed work on the development of guidance procedures for monitoring the stability and purity of pesticide RMs before and after RMPs' specified expiry dates for supporting the extended use of RMs is thus relevant and timely for consideration by the Codex Committee on Pesticide Residues (CCPR). It is also widely recognised by the members of EWG that the proposed new work should also cover the developmet of the guidance procedures for monitoring the stability and purity of the stock solutions of the related RMs and the establishment of the expiry dates of these stock solutions, which are critical for supporting the daily operation of pesticide residue laboratories.

Main Aspects to Be Covered

8. The central objective is to use the RMs beyond their specified expiry dates for pesticide residue analysis in food and environmental samples. The main aspect of this proposed new work is to develop comprehensive harmonized guidance which enable the laboratories to monitor the stability and purity of the pesticide RMs and their stock solutions during prolonged storage. Such harmonised guidance forms the technical basis for extended use of RMs beyond their expiry dates as well as for establishment of expiry dates of stock solutions.

Assessment against the *Criteria for the Establishment of Work Priorities*General Criterion

9. General criterion of the proposed new work is to monitor and verify the purity of RMs as specified by RMPs before and after expiration through robust analytical protocols so that such materials that retain their purity as per the CoAs even after expiry can continue to be used as valid RMs. Another aspect of the proposed work is to monitor the stability of the stock solutions used for pesticide residue analysis to ensure that the concentrations of individual pesticides to enable the establishment of their expiry dates, within which these solutions continue to be valid for the accurate and reliable determination of pesticide residue levels.

Criteria Applicable to General Subjects

- i) Scope of Work and Establishment of Priorities between the Various Sections of the Work
10. The CCPR recognizes the significance of RMs in the analysis of pesticide residues in food commodities and in the soil and aquatic environment. However, the lack of data on the stability and purity of RMs during prolonged storage, and the absence of guidance procedures for determining their stability and purity prevent the use of RMs beyond the expiry dates as specified by RMPs. Likewise, the lack of consistent approach for monitoring the stability and purity of stock solutions of these RMs bring about uncertainties in setting the expiry dates for these solutions to support the daily operation of pesticide residue labs. Scope of the work shall therefore be prioritized stepwise as below: (a) defining the acceptance criteria for extending the use RMs beyond their expiry dates specified by RMPs, (b) developing guidance procedures along with storage conditions for monitoring the stability and purity of the RMs at different time intervals within and beyond the expiry dates to extend the use of RMs based on the defined acceptance criteria, (c) defining the acceptance criteria for establishment of expiry dates for stock solutions, (d) developing guidance procedures along with storage conditions for monitoring the stability and purity of the stock solutions to establish the expiry dates of stock solutions based on the defined acceptance criteria
- ii) Amenability of the subject of the proposal to standardization
11. The expiry dates of the pesticide RMs and stock solutions are dependent on their types, classes, structure moieties, and storage conditions like temperature, humidity, media, presence of air and light etc. Pesticide analysis is performed globally, and these guidance procedures can be applicable to all the laboratories with varying levels of technical capabilities. There are attempts in many countries in promoting good laboratory practices, e.g. European Reference Materials (ERM) Application Notes regarding the handling and use of RMs and stock solutions. The proposed new work is thus considered amenable to standardization for benefitting many member states, especially the developing countries.
- iii) Consideration of the global magnitude of the problem or issue
12. Since pesticides are used globally, the development of guidance procedures for setting the expiry dates of pesticide RMs and stock solutions through monitoring their stability and purity at regular intervals for extended use is of global relevance to ensure robust food safety control and for trustworthy practices in international agri-food trade.
- iv) The relevance to the Codex strategic objectives
13. The Codex Strategic Plan 2020-2025 underpins the high priority that continues to be placed on food safety and quality by FAO and WHO and guides the Codex Alimentarius Commission in carrying out its responsibilities to fulfil the mandate of protecting consumer health and ensuring fair practices in the food trade. The use of reliable RMs and related stock solutions for supporting pesticide residue analysis is important for the establishment and implementation of Codex maximum residue limits (CXLs) to achieve the strategic goals of Codex. The development of guidance procedures on monitoring the stability and purity of pesticide RMs and stock solutions for setting expiry dates for the above materials during prolonged storage with high confidence is hence a key technical enabler towards Codex strategic objectives.

Information on the Relation between the Proposal and Other Existing Codex Documents as well as Other Ongoing Work

14. The guidance procedures to be developed complement the following endorsed Codex documents in the area of pesticide residue analysis:
 - Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food and Feed (CXG 90-2017)
 - Guidelines on Estimation of Uncertainty of Results (CAC/GL 59-2006, version 2011)
 - Guidelines on Good Laboratory Practice in Pesticide Residue Analysis (CAC/GL 40-1993, version 2010)

Identification of Any Requirement for and Availability of Expert Scientific Advice

15. Expert knowledge exists among CCPR members, pertinent national and international competent authorities and industry observers.

Identification of Any Need for Technical Input to the Standard from External Bodies

16. For the elaboration of this document, the advice from FAO, WHO and the JMPR Secretariat will be taken as and when required. Other documents issued by international organizations such as the relevant SANTE, ISO guidelines and research reports in literature have been used as a reference to develop the guidance procedures.

The Proposed Timeline for Completion of the New Work, including the Start Date and the Proposed Date for Adoption by the Commission

17. Subject to approval by the Codex Alimentarius Commission, the set guidance document will be submitted for consideration at CCPR55 (2024) and finalized for adoption by CAC in 2026 or earlier.